K043249

MAY 25 2005

Atrion Medical Products, Inc.
1426 Curt Francis Road
Post Office Box 564
Arab, AL 35016
Tel 256 586 1580
Fax 256 586 8529

Atrion
Medical

11. 510(k) SUMMARY

Date of Preparation:	April 30, 2005
Device Names:	Atrion NeedleVISE™ Large-Bore Sharps Securing Device
Common Name:	Accessory to a Needle, Hypodermic, Single Lumen
Classification Name:	Accessory to single lumen hypodermic needle 21 CFR 880.5570, ProCode 80 FMI
Manufacturer:	Atrion Medical Products, Inc. 1426 Curt Francis Road Arab, AL 35016
Contact:	Mr. Dan Clark, Atrion Medical Products, Inc. 1426 Curt Francis Road Arab, AL 35016 Telephone: (256) 586-1580, Fax: (256) 586-8529
Predicates:	Devon Industries, Inc. Point-Lok® Needle Protection Device (K946289)

Device Description:

The NeedleVISE™ Large-Bore Sharps Securing Device is a single patient procedure use, disposable device used for securing needles.

The healthcare professional using only one hand can render the sharps harmless. The purpose of the NeedleVISE™ Large-Bore Sharps Securing Device is to provide a means to make engineered sharps control protection available for all instances in which introduction of contaminated sharps containers is not acceptable.

Intended Use:

The Atrion NeedleVISE™ Large-Bore Sharps Securing Device is intended for use in various clinical procedures as a sharps securing device for contaminated needles that do not have integral engineered sharps safety systems.

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Technological Characteristics:

The NeedleVISE™ Large-Bore Sharps Securing Device has similar materials as the predicate device and the technological characteristics are unchanged from the predicate device, as they both lock the used sharps into a metal retaining clip contained within a plastic housing.

Summary of Testing:

The NeedleVISE™ Large-Bore Sharps Securing Device tests included mechanical property testing to assess impact, puncture resistance and pull out force. The results showed the NeedleVISE™ Large-Bore Sharps Securing Device to be substantially equivalent to the predicate device. Clinical utility was evaluated in field trials designed to assess ease of use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2005

Mr. Dan Clark
Vice President
Atrion Medical Products, Incorporated
1426 Curt Francis Road
P.O. Box 564
Arab, Alabama 35016

Re: K043249
Trade/Device Name: Atrion NeedleVISE™ Large-Bore Sharps Securing Device
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: April 30, 2005
Received: May 2, 2005

Dear Mr. Clark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

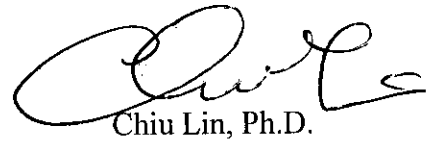
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

12. INDICATIONS FOR USE STATEMENTS

b. NeedleVISE Large-Bore Sharps Securing Device

Indications for Use

510(k) Number (if known): K043849

Device Names: Atrion NeedleVISE™ Large-Bore Sharps Securing Device

Indications For Use:

The NeedleVISE™ Large-Bore Sharps Securing Device is intended for use in various clinical procedures as a sharps securing device for contaminated needles that do not have integral engineered sharps safety systems.

Prescription Use ___X___ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGEIFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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